

PATIENT INFORMATION LEAFLET

Adcal-D3[®] Caplets

Calcium carbonate (750 mg) and vitamin D3 (200 I.U.)

Film-coated tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Adcal-D3 Caplets are and what they are used for

Adcal-D3 Caplets contain calcium and vitamin D3 which are both essential for healthy bones and teeth. Adcal-D3 Caplets provide extra calcium and vitamin D3 to your diet. It is therefore used in conditions where your body's calcium and vitamin D levels need to be increased.

Adcal-D3 Caplets can be prescribed by doctors for certain bone conditions, for example, osteoporosis.

Studies show that taking calcium and vitamin D3 over a long time can prevent hip and other non-vertebral bone fractures in later life.

2. What you need to know before you take Adcal-D3 Caplets

Do not take Adcal-D3 Caplets :

- if you are allergic to calcium carbonate, vitamin D3 or any of the other ingredients of this medicine (listed in section 6).
- if you have higher than normal levels of calcium in your blood (hypercalcaemia). Your doctor will be able to tell you if you do.
- If you have severe kidney failure

Warnings and precautions

Talk to your doctor or pharmacist before taking Adcal-D3 Caplets.

Tell your doctor or pharmacist if you:

- Have osteoporosis (thinning of the bones) due to long periods of inactivity, such as long-term bed rest.
- Have problems with your kidneys, for example kidney stones.
- Have higher than normal levels of calcium in your urine (hypercalciuria). If you are unsure your doctor will advise you.
- Have sarcoidosis (inflammation that produces lumps of cells in various organs in the body). Your doctor will be able to tell you if you do.

- Have previously been told by your doctor that you have an intolerance to some sugars.
- Are taking any other medication, even those you may have bought for yourself without prescription.

Other medicines and Adcal-D3 Caplets

Tell your doctor if you are taking calcium supplements or antacids for indigestion, digitalis drugs (e.g. Lanoxin), diuretics or corticosteroids.

If you are taking thyroxine, bisphosphonates, iron or fluoride medicines, tetracycline or quinolone antibiotics make sure your doctor knows this. When taking these medicines leave a period of about 4 hours before taking your Adcal-D3 Caplets. Do not take any of these listed medicines at the same time as your Adcal-D3 Caplets.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

In pregnancy or when breast feeding, Adcal-D3 Caplets should only be used under medical supervision. Ask your doctor or pharmacist for advice before taking any medicine.

Adcal-D3 Caplets with food

This medicine should not be taken within 2 hours of eating foods rich in oxalic acid (e.g. spinach and rhubarb), phosphate (e.g. bran), or phytic acid (e.g. whole cereals).

3. How to take Adcal-D3 Caplets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults, elderly and children over 12 years of age – Swallow 2 caplets twice daily, ideally two caplets in the morning and two in the evening.

Children under 12 – **Do not** give Adcal-D3 Caplets to children under 12 years.

If you take more Adcal-D3 Caplets than you should - You should only take what your doctor recommends. If you take too many caplets contact your doctor or pharmacist if you can do so. If not, go to the nearest hospital casualty department immediately, taking the pack and remaining tablets with you.

If you forget to take Adcal-D3 Caplets - If you forget to take your caplets, take them as soon as possible and then continue to take them as normal. Do not take a double dose to make up for forgotten caplets.

If you stop taking Adcal-D3 Caplets – Always talk to your doctor or pharmacist before you stop taking the caplets.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Frequency not known (frequency cannot be estimated from the available data):

- Allergic reactions - symptoms include itching, wheezing, rash, swelling of the tongue or throat. If you have an allergic reaction **stop taking the tablets and seek medical attention immediately**.

Rare side effects (may affect up to 1 in 1,000 people):

- Constipation, wind, feeling sick, stomach ache, diarrhoea
- Skin rash
- Hypercalcaemia (too much calcium in your blood) or hypercalciuria (too much calcium in your urine)

If you are on long term treatment your doctor may from time to time wish to check the level of calcium in your blood and take urine samples to monitor kidney function.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme:

Website: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Adcal-D3 Caplets

- Keep this medicine out of sight and reach of children.
- Do not store above 25°C. Store in the original package.
- Do not use this medicine after the expiry date that is printed on the carton label has passed. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and further information

What Adcal-D3 Caplets contain

- The active substances are calcium carbonate (750 mg equivalent to 300 mg calcium) and vitamin D3 (200 I.U. equivalent to 5 micrograms of colecalciferol).
- The other ingredients in the tablet core are colloidal silicon dioxide, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, modified food starch, sucrose, sodium ascorbate, medium chain triglycerides, silicon dioxide, DL-alpha-tocopherol and pregelatinized starch.
- The orange film-coat contains hypromellose, polydextrose, acacia, talc, titanium dioxide, iron oxide yellow and iron oxide red.

What Adcal-D3 Caplets look like and contents of the pack

Adcal-D3 Caplets are orange capsule-shaped film-coated tablets ('caplets') provided in bottles of 112 or 224 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Kyowa Kirin Limited
Galabank Business Park

Manufacturer:

NextPharma
allphamed Pharbil Arzneimittel GmbH

Galashiels
Scotland
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Additional information

If you have been prescribed Adcal-D3 Caplets for the treatment or prevention of osteoporosis and would like further information you should speak to your doctor or pharmacist.

This leaflet was last revised in 02/2017